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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,857	03/11/2004	James F. Brown	832_001 DIV3	7179
25191 7590 01/09/2007 BURR & BROWN PO BOX 7068 SYRACUSE, NY 13261-7068			EXAMINER CHIN, CHRISTOPHER L	
			ART UNIT	PAPER NUMBER
			1641	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/798,857

Applicant(s)

BROWN, JAMES F.

Examiner

Christopher L. Chin

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 3/11/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 5-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5-8 are vague because they do not appear to further limit the claims from which they depend. The limitations recited in these claims appear to be present in the claims from which they depend.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Art Unit: 1641

3. Claims 1-8 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,143,496. Although the conflicting claims are not identical, they are not patentably distinct from each other because patent '496 claims a method with essentially the same limitations as the instant invention.

Patent '496 claims:

A method comprising:

providing a sample containing at least one target nucleic acid molecule to be amplified and constituents for enabling amplification of the target nucleic acid molecule;

loading the sample into a device, said device having multiple sample containers;

subdividing the sample in the device into a plurality of sample portions, one sample portion in each of the multiple sample chambers, wherein at least one of said sample portions loaded into a respective sample chamber includes said at least one target nucleic acid molecule;

subjecting the sample portions loaded into the respective sample chambers to a homogeneous assay for detecting the amplified product including conditions under which amplification of said at least one target nucleic acid molecule occurs and a detectable amplified product of each target molecule in the sample chamber is formed;

detecting amplified product in said sample chambers; and

determining the number of said sample chambers that contain a sample portion from which said amplified product is formed, wherein

Art Unit: 1641

said sample chambers each have one or more dimensions such that the sample chambers that contain at least one target molecule before amplification attain a detectable concentration of amplified product in said sample chambers after a single round of amplification.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Cottingham.

Cottingham (US Patent 5,795,748) discloses a method for carrying out an integrated nucleic acid amplification and homogeneous nucleic acid fluorescence polarization assay on a liquid biological sample. The method comprises the steps of providing a sample well having a substantially flat, upwardly facing, bottom interior surface. Introducing a liquid biological sample into the sample well. Bringing the liquid sample into contact with a dried nucleic acid amplification reagent and a dried homogeneous nucleic acid fluorescence polarization assay reagent. Sealing the well.

Art Unit: 1641

Incubating the sample well to allow the sample to react with the amplification reagent and the fluorescence polarization assay reagent. And detecting fluorescence polarization in the sample (col. 3, lines 46-67).

6. Claims 1-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Cottingham.

Cottingham (US Patent 5,948,673) discloses a method for carrying out an integrated nucleic acid amplification and homogeneous nucleic acid fluorescence polarization assay on a liquid biological sample. The method comprises the steps of providing a sample well having a substantially flat, upwardly facing, bottom interior surface. Introducing a liquid biological sample into the sample well. Bringing the liquid sample into contact with a dried nucleic acid amplification reagent and a dried homogeneous nucleic acid fluorescence polarization assay reagent. Sealing the well. Incubating the sample well to allow the sample to react with the amplification reagent and the fluorescence polarization assay reagent. And detecting fluorescence polarization in the sample (col. 4, lines 25-45).

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher L. Chin whose telephone number is (571) 272-0815. The examiner can normally be reached on Monday-Thursday.

Art Unit: 1641

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Christopher L. Chin
Primary Examiner
Art Unit 1641

1/2/07